K113756

510(k) Summary

MAR 14 2012

Date: January 25, 2012

Manufacturer:
Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758

Contact Person:
Teffany Hutto
Manager, Regulatory Affairs
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Product	Classification	Product Codes
Highly Cross Linked Patella with Vitamin E	Class II	JWH, OIY

Product Code	Regulation and Classification Name
JWH	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560
OIY	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560

Description: This submission is to request clearance for a line extension to the current patella product line to include a highly cross linked polyethylene patella infused with pure liquid pharmaceutical grade alpha-tocopheral.

Indications for Use:

Joint replacement is indicated for patients suffering from disability due to:
- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;
- treatment of fractures that are unmanageable using other techniques.

This device may also be indicated in the salvage of previously failed surgical attempts.
This system is to be used for cemented applications.

Predicate Devices:

DJO Surgical Metal Backed Patella - K932246
DJO Surgical Tri-Peg Patella - K905613
DJO Surgical Movation Patella - K100900
DJO Surgical 3DKnee Insert - K091956

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same design features, materials, indications sterilization, packaging and intended use.

Non-Clinical Testing: Previous mechanical testing demonstrated the device's ability to perform under expected conditions. Testing included mechanical characterization testing, push out, lever out, torsion, Izod impact, small punch, tensile, FTIR, wear, animal implant for toxilogical response, and cytotoxicity. Material characterization testing did not need to be repeated as identical material was cleared in K091956. Testing for subluxation, and contact stresses was found not to be required due to design equivalence.

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Encore Medical, L.P.
% Ms. Teffany Hutto
Regulatory Affairs Manager
9800 Metric Boulevard
Austin, Texas 78758

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Re: K113756
Trade/Device Name: Highly Cross Linked Patella with Vitamin E
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: OIY, JWH
Dated: January 25, 2012
Received: January 26, 2012

Dear Ms. Hutto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K113756

Device Name: Highly Cross Linked Patella with Vitamin E

Indications for Use:

Highly Cross Linked Patella with Vitamin E
Indications for Use

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113756